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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/619,901 | 07/19/2000 | Michael J. Botich | 1032-P00101US9 | 2085 |

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DANN, DORFMAN, HERRELL & SKILLMAN
1601 MARKET STREET
SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

WILLIAMS, CATHERINE SERKE

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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3763

16

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/619,901

Applicant(s)

BOTICH ET AL.

Examiner

Catherine S. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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Response to Arguments

Applicant's arguments, see paper # 15, filed 12/08/03, with respect to the rejection(s) of claim(s) 45-73 using Shaw (US Pat# 5,632,733) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Ridderhein et al (US Pat# 4,955,870).

Additional, the previous double patenting rejection over patent 6,096,005 has been withdrawn. The other outstanding double patenting rejections are still of record and appear below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45, 48-50, 69 and 72 rejected under 35 U.S.C. 102(e) as being anticipated by Ridderhein et al (US Pat# 4,955,870).

Ridderhein discloses a medical device having a needle (12) operable between a projected position and a retracted position (see figures 9a-9e), a hollow barrel (10), a plunger (14) with a cavity and a cover (see distal end of the plunger 14, figure 2), and a biasing spring element (56). The biasing element biases the needle toward the retracted position when the cover on the plunger has been severed by moving into an end position and contacting the needle housing. See

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figure 9e. Once the cover has been severed the needle and spring are retracted into the cavity of the plunger. The device also includes a first and second threaded mated connectors (see figure 2 and 3) for attaching the needle to the barrel.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45, 50-51, 56-58, 60-64 and 66-69 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10-19 and 30-32 of U.S. Patent No. 6,179,812. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent both claim a barrel with a first connector (barrel means), a needle assembly with spring and second connector (spring holding means) that engages the first connector and a plunger with a cavity and a breakable end that is severed with the plunger is depressed into the bottom of the barrel and locked. The method steps are inherent to the claims of the above patent.

Claims 45-48, 50-54, 56-58, 60-64 and 66-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of U.S.

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Patent No. 4,994,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent both claim a barrel with a first connector (barrel means), a needle assembly with spring and second connector (spring holding means) that engages the first connector and a plunger with a cavity and a breakable end that is severed with the plunger is depressed into the bottom of the barrel. Further, both further claim a needle retainer with fingers which are spread by the plunger to release the needle. Claim 16 of the above patent claims that the spring holding means "can easily be attached and removed from the barrel means" (releasably connected: claim 54 of instant application). The method steps are inherent to the claims of the above patent.

Claims 45-47, 50-53, 56-59, 61-64 and 67-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 23 of U.S. Patent No. 5,407,431. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent both claim a barrel with a first connector (barrel means), a needle assembly with spring and second connector (spring holding means) that engages the first connector and a plunger with a cavity and a breakable end that is severed with the plunger is depressed into the bottom of the barrel. Further, both further claim a needle retainer with fingers which are spread by the plunger to release the needle. The method steps are inherent to the claims of the above patent.

Claims 45-47, 50-53, 56-58, 60-64 and 66-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,188,599. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and the above patent both claim a barrel

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with a first connector (barrel means), a needle assembly with spring and second connector (spring holding means) that engages the first connector and a plunger with a cavity and a breakable end that is severed with the plunger is depressed into the bottom of the barrel. Further, both further claim a needle retainer with fingers which are spread by the plunger to release the needle. The method steps are inherent to the claims of the above patent.

Claims 49, 55, 59 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of U.S. Patent No. 4,994,034 in view of Alter et al (4,919,652).

Claims 49, 55 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 12-16 of U.S. Patent No. 5,407,431 in view of Alter et al (4,919,652).

Claims 49, 55, 59 and 65 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,188,599 in view of Alter et al (4,919,652).

The claims of the instant application are unpatentably similar to the patents as described above. While the above patents do not claim that the "means" for connection is a threaded connector, one is considered obvious. The above patents show and discloses a push/frictional connection between the needle assembly and the barrel of the syringe. See figures. However, it would have been obvious to substitute the push/frictional connection of the above patents with a threaded connector. Threaded connectors are well known in the art for attaching needle assemblies to syringe barrels. Alter et al discloses such a connection. Additionally, the needle

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assembly of Alter, once threaded into the barrel, protrudes into the interior of the barrel much like the needle assemblies of the above patents. The motivation for the substitution would have been to use a well-known mechanism of needle attachment.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams 
March 5, 2004


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700